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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,739	07/11/2001	Phillip H. Paul	SD-8245.2 DIV	9843

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,739

Applicant(s)

PAUL ET AL.

Examiner

Jan M. Ludlow

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13, 15 and 16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13, 15, drawn to a method for injecting a sample into a chromatography column, classified in class 436, subclass 161.
- II. Claim 16, drawn to a method of providing a sample of defined volume, classified in class 426, subclass 180.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require, e.g., a sample injector that provides flow through a flow channel. The subcombination has separate utility such as use in a system not fabricated on a substrate.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
5. Newly submitted claim 16 is directed to an invention that is independent or distinct from the invention originally claimed for the above reasons:

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 16 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (5858195).

5. Ramsey teaches a method of injection into a separation column (col. 11, line 49- col. 12, line 30) using electrokinetic pumping (abstract, line 9). Referring to figure 6, buffer flows from reservoir 12B to reservoir 20B through separation column 34B.

Analyte flows from reservoir 16B to reservoir 18B. In "floating" mode, a potential differential is applied between reservoirs 16B and 18B to draw analyte through intersection 40B, while no differential is applied between reservoirs 12b and 20B. It is the examiner's position that with no potential difference between reservoirs 12B and 20B, flow of the running buffer is substantially stopped. Then in run mode, a differential is applied between 12B and 20B to inject the contents of the intersection by flowing the buffer to pass the analyte through the separation column, which may be a chromatography column (col. 10, line 17). It is taught that a second sample plug may be injected (col. 12, lines 20-25).

6. Ramsey fails to explicitly teach running the buffer through the separation column prior to injection.

7. It would have been obvious to inject a second sample plug through the column of Figure 6 in order to test a second sample as taught by Ramsey. In injecting a second sample, the sequence of events suggested is load, run, load, run, where the buffer is running through the column in run mode and stopped in load mode. Thus the running of the first sample constitutes the first flushing step, the loading of the second sample

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stops buffer flow and initiates analyte flow and running of the second sample constitutes injection and restarting of the buffer flow.

8. Claims 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey ('195) in view of Ramsey (6376181).

9. Ramsey '195 fails to explicitly teach hydraulic pumping.

10. Ramsey '181 teaches that electrokinetic pumping and hydraulic pumping are interchangeable in microfluidic devices (col. 5, lines 35-45).

11. It would have been obvious to use hydraulic pressure in place of electrokinetic pumping to move fluids through the device of Ramsey '95 in order to use alternative known pumping means as taught by Ramsey '181.

12. Claims 13, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey ('195) in view of Parce '259

13. Ramsey '195 fails to explicitly teach hydraulic pumping.

14. Parce '259 teaches that electrokinetic pumping and hydraulic pumping are interchangeable in microfluidic devices (e.g., claim 11).

15. It would have been obvious to use hydraulic pressure in place of electrokinetic pumping to move fluids through the device of Ramsey '95 in order to use alternative known pumping means as taught by Parce '259.

16. Applicant's arguments filed August 8, 2003 have been fully considered but they are not persuasive.

17. The statement concerning common ownership overcomes the rejections involving Arnold and Paul, but applicant has not addressed the remaining rejections.

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Applicant discloses that an electrokinetic pump provides the instant hydraulic pressure. Ramsey teaches an electrokinetic pump. It is therefore the examiner's position that Ramsey inherently provides hydraulic pressure in that the electrokinetic pump generates pressure to move liquids in the system. In the event that this is not the case, alternative rejections have been made.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
October 19, 2003